Declaration of Conformity

Manufacturer:	**PRIME4DIA Co., Ltd** : #930, 415 Heungan-daero, Dongan-gu, Anyang-si, Gyeonggi-do, 14059, Republic of Korea
EC-Representative:	**MT Promedt Consulting GmbH** Altenhofstrasse 80, D-66386 St. Ingbert, Germany
Product:	**P4DETECT COVID-19 IgM/IgG** **- EDMA Code: 15 04 80 90 00** **(Other viral antigen/antibody detection)**
Classification:	**Other IVD** **(Neither Listed in Annex II of IVDD, nor self-testing device)**
Conformity Assessment Route:	**ANNEX III of IVDD**

We here with declare that the above mentioned products meet the provisions of the council Directive 98/79/EC for In Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	Directive 98/79/EC for IVD products, EN ISO13485:2016, EN ISO14971:2012, EN ISO 15223-1:2016, EN 13612:2002, EN 13975:2003, EN 13641:2002, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015
Place, Date of Issue:	Gyeonggi-do, Republic of Korea , June, 01, 2020

Signature:

KYUHA OH

CEO/President

CE

This declaration of conformity is issued under the sole responsibility of the manufacturer

PRIME4DIA Co., Ltd.